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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/478,153	06/07/1995	MICHAEL J. ADANG	MPS-11-83D2D	6814
23557 7590 02/15/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER FOX, DAVID T	
			ART UNIT	PAPER NUMBER
			1638	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/15/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

08/478,153

Applicant(s)

ADANG ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Restriction/Election

Applicant's election without traverse of Group I in the reply filed on 25 January 2007 is acknowledged.

Specification Objections

Pages 1 and 98 of the specification are objected to for failing to include the current status of the parent or related applications. The specification should be amended to insert --- , now Abandoned--- or --- , now US Patent X--- after the filing dates of each application, as appropriate. Furthermore, page 98 of the specification, as amended by the preliminary amendment of 10 January 2006, should be amended to include the filing date of related application 07/076,339 which was incorporated by reference. All specification amendments should comply with 37 CFR 1.121(b).

Furthermore, page 5 of the preliminary amendment of 10 January 2006 is objected to for its amendment of page 25 of the specification. Specifically, page 25 of the specification has been amended to introduce a Brief Description of newly added Figure 4 from incorporated application no. 07/076,339. While such an amendment in principle is acceptable, this amendment is confusing in its recitation of "abbreviations...GRM_{gn} are described in Table 14", since Table 14 does not recite "GRM_{gn}". Correction is requested. New matter should be avoided.

Title and Abstract Objections

The Title and Abstract are objected to for not being sufficiently descriptive or specifically relating to Applicant's newly claimed invention. The Title should be

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amended to insert ---Cotton--- before "Plants". Similarly, line 1 of the Abstract should be amended to insert ---cotton--- before "plant".

Drawing Objections

Figure 1 submitted 07 June 1995 is objected to for its use of small and indistinct characters. Applicant is requested to submit a substitute Figure 1.

Figures 2-3 submitted 07 June 1995, and Figure 4 submitted 10 January 2006, are deemed acceptable and are hereby APPROVED.

Effective Filing Date

The effective filing date for transforming and regenerating Class 2 cotton genotypes, which include non-Coker agronomic varieties such as Acala, Delta and Plains types (per page 98 of the specification, as incorporated by reference from application no. 07/076,339 via the amendment of 10 January 2006), with an insecticidal protein gene including a *Bacillus thuringiensis* gene, is 26 September 1983, the filing date of parent application 06/535,354.

Terminal Disclaimer

Applicant's Terminal Disclaimer of 10 January 2006, disclaiming related patents 6,660,914 and 6,573,437 which claim transformed Class 2 cotton genotypes including Acala, has been approved.

Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite in its recitation of "phenotype is expression of an insecticidal protein" which is confusing and contrary to art-recognized definitions, since a phenotype refers to a trait rather than protein expression. The following amendment would obviate this rejection.

In the last line of claim 24, insert ---insect resistance conferred by--- before "expression".

Claim 25 is indefinite in its recitation of "said insecticide structural gene" in lines 2-3, which lacks antecedent basis in the claim. Amendment of claim 25 to insert ---structural--- before "gene" in line 2 would obviate this rejection.

All claim amendments should comply with 37 CFR 1.121(c).

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is broadly drawn to a cotton plant transformed with any gene from any source including animals, plants, bacteria, viruses or fungi; said gene being of any sequence and encoding any protein or transcription product of any sequence. In contrast, the specification only provides guidance for a single gene from the bacterium *Bacillus thuringiensis* which encodes the insecticidal crystal protein depicted in Figure 1. No guidance is provided regarding the identification, isolation or characterization of any other insecticidal protein-encoding gene from any other source and of any other sequence, encoding any insecticidal protein of any other sequence. No guidance is provided regarding the conserved structural features, i.e. sequence domains, present throughout this broad genus which are associated with the function of conferring insect resistance on plants transformed therewith.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Enablement

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is broadly drawn to a cotton plant transformed with any gene from any source including animals, plants, bacteria, viruses or fungi; said gene being of any sequence and encoding any protein or transcription product of any sequence. In contrast, the specification only provides guidance for a single gene from the bacterium *Bacillus thuringiensis* which encodes the insecticidal crystal protein depicted in Figure 1. No guidance is provided regarding the identification, isolation or characterization of any other insecticidal protein-encoding gene from any other source and of any other sequence, encoding any insecticidal protein of any other sequence. No guidance is provided regarding the evaluation of said multitudes of non-exemplified genes for their ability to confer insect resistance to plants transformed therewith.

It is unpredictable whether genes not from *Bacillus thuringiensis* and not encoding *B.t.* crystal proteins are able to confer insect resistance to plants transformed therewith. As an example of the state of the art up to and after the effective filing date of the instant application, Pang et al (1992) teach that expression of a scorpion-derived gene encoding an insecticidal protein in plants failed to confer insect resistance to said transformed plants (see, e.g., page 165, Abstract).

Even when *Bacillus thuringiensis* genes encoding *B.t.* crystal proteins are used to transform plants, the ability of said genes to confer insect resistance is unpredictable. Dandekar et al (1994) teach that expression of *Bacillus thuringiensis* crystal protein-encoding gene failed to confer insect resistance to walnut plants transformed therewith (see, e.g., page 151, Abstract; page 153, column 1, top two paragraphs; paragraph bridging pages 153 and 154; paragraph bridging pages 154 and 155; page 157, paragraph bridging the columns; paragraph bridging pages 159 and 160).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate a multitude of non-exemplified insecticidal genes from a multitude of non-exemplified sources, including a multitude of non-exemplified *B.t.* crystal protein-encoding genes; and to evaluate the ability of said genes to successfully confer insect resistance to plants transformed therewith.

Conclusion

The claims are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest cotton transformation with genes encoding insecticidal proteins for the production of insect-resistant cotton plants, particularly cotton plants of the Class 2 genotype; as evidenced by commonly owned issued patents 6,660,914; 6,573,437; and 6,943,282.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795.

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The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 9, 2007

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

